

REMARKS

Status of the Claims

Claim 1 has been amended; claims 4, 5 and 21-29 have been withdrawn from consideration; claims 30 and 31 have been cancelled; and claims 32 and 33 have been added. Thus, claims 1-29, 32 and 33 are pending. Claims 1-3 and 6-20 stand rejected.

Drawings

Corrected drawings are submitted herewith.

Requirement to Correct Sequence Listing

A corrected sequence listing in both paper and computer readable formats is submitted herewith. Also submitted is a declaration that the sequence listing in both formats is the same.

Amendment and Addition of Claims

The subject matter of claim 1 and new claims 32 and 33 contain no new matter and are at least supported by the specification at page 4, lines 13-17.

Rejection of Claims 1-3 and 6-20 under 35 U.S.C. §112, First Paragraph

In the Office Action claims 1-3 and 6-20 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicant points out that the specification discloses how to both make and use the compounds recited in the claims. Methods of making or isolating compositions comprising N-glycolylneuraminic acid or derivatives thereof are taught at least at page 2 line 5 and lines 10-13, page 4 lines 13-15, page 4 line 18 to page 5

line 10, page 6 line 28 to page 7 line 18, Figure 2, Examples 1 and 3 (pages 7-15), and original claims 19 and 20 of the specification. Furthermore, the specification teaches how to administer (e.g., use) such compositions at least at page 2 lines 2-5 and lines 7-8, page 5 lines 13-14, page 5 line 22 to page 6 line 5, and original claims 6-10 and 12-15. The Office Action points to the difficulty of treating HIV infection, yet such an argument applies to prior art methods. It is believed that Applicant has complied with the enablement requirement. Applicant respectfully requests that this rejection be withdrawn.

Rejection of Claims 1-3 and 6-15 under 35 U.S.C. §112, First Paragraph

In the Office Action claims 1-3 and 6-15 were rejected under 35 U.S.C. §112, first paragraph, as failing to provide an adequate written description of the recitation of “derivative.” Although Applicant disagrees with the position of the USPTO, claim 1 has been amended to recite that “said derivative is phosphorylated N-glycolylneuraminic acid, sulfated N-glycolylneuraminic acid, a salt of N-glycolylneuraminic acid, or O-glycolylneuraminic acid” in order to advance the prosecution of instant application without prejudice to prosecute a claim or claims having a different scope in another application. Applicant respectfully requests that this rejection be withdrawn.

Rejection of Claims 1-3 and 6-20 under 35 U.S.C. §102(f)

It is asserted in the Office Action that the invention of claims 1-3 and 6-20 was not invented by the Applicant. Applicant had confidential meetings after the submission of provisional applications (U.S. Provisional Application Serial Nos. 60/011,552 and 60/037,976, filed February 13, 1996 and February 12, 1997, respectively) and before the submission of U.S.

Patent Application Serial Nos. 09/015,830 (January 29, 1998) and 09/474,677 (December 29, 1999), and U.S. Provisional Application Serial No. 60/114,540 (December 29, 1998). None of the recipients are inventors of any of the claims of instant invention. See ¶ 6 of Declaration under 37 C.F.R. 1.132 by Dr. Yash Sharma, dated March 17, 2006. Applicant respectfully requests that this rejection be withdrawn.

Rejection of Claims 1-3 and 6-20 under 35 U.S.C. §102(f)

It is asserted in the Office Action that the invention of claims 1-3 and 6-20 was not invented by the Applicant based on Minarcik's disclosure. Dr. Minarcik assisted Applicant; however, both Applicant and Dr. Minarcik state that Dr. Minarcik is not an inventor of any of the claims of instant invention. See ¶ 7 of Declaration under 37 C.F.R. 1.132 by Dr. Yash Sharma, dated March 17, 2006. Dr. Minarcik states that the “birth, formulation, ideas, hard work, ... were wholly the work of [Dr. Yash Sharma].” See ¶ 7 and Tab A of Declaration under 37 C.F.R. 1.132 by Dr. Yash Sharma, dated March 17, 2006. It is clear that Dr. Minarcik is not an inventor. Applicant respectfully requests that this rejection be withdrawn.

Rejection of Claims 1-3 and 6-16 under 35 U.S.C. §103(a)

Claims 1-3 and 6-16 were rejected under 35 U.S.C. §103(a) as being unpatentable in view of Minarcik (1996 August 26, sci.med.aids mailing list). In the supplied mailing list, Dr. Minarcik speculates, at the time of his comments, that “[c]urrent ongoing analyses indicate that the apparent ‘active’ fraction of Lukor is a relatively small (molecular weight 200-500) molecule....” At the time of the writing, Minarcik did not know the identity of the compound.

In response to Minarcik's statements, Charles McCarthy posted the comment on the same page questioning the credibility of his assertions,

An explanation for the varying molecular weight of this non peptide material would also be interesting. Are these esters with varying lengths of acid or alcohol moieties? You have to be very skeptical about compounds that are purported to disintegrate virions without doing any damage to host cells which coincidentally are composed of similar materials.

The active ingredient had not been isolated and could not be described. The identity was unknown. Only later, was the active ingredient isolated, characterized, and identified, and found to be N-glycolylneuraminic acid.

Claims 1-3 and 6-16 are directed to use of N-glycolylneuraminic acid in the treatment of a viral infection, not to the use of LUKOR, which is a baboon blood cell lysate. There are many thousands of variations of manners, methods, and techniques to identify compounds with the successful outcome being by no means guaranteed. It is urged that the recitation of claim 1, "A method for treating a viral infection in a subject, said method comprising administering N-glycolylneuraminic acid or a derivative thereof to said subject in an amount effective to treat said viral infection, wherein said derivative is phosphorylated N-glycolylneuraminic acid, sulfated N-glycolylneuraminic acid, a salt of N-glycolylneuraminic acid, or O-glycolylneuraminic acid," would not have been obvious to one of ordinary skill in the art, at the time the invention was made based on Minarcik's statements. Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

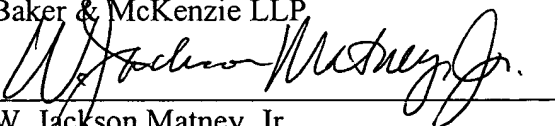
In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response; please charge any deficiency in fees or credit any overpayments to Deposit Account No. 50-3420 (95176571-002001).

Respectfully submitted,

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